

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

1. (Currently Amended) A lyophilized preparation comprising a hepatocyte growth factor, a stabilizing agent comprising arginine, lysine, histidine, glutamine, proline, glutamic acid, or aspartic acid, or a pharmacologically acceptable salt thereof for preventing formation of [[a]] an aggregate of the hepatocyte growth factor, sodium chloride, and a buffering agent, which is prepared from an aqueous solution containing the hepatocyte growth factor at a concentration lower than 5 mg/mL.
2. (Canceled)
3. (Currently Amended) A lyophilized preparation comprising a hepatocyte growth factor, a stabilizing agent comprising arginine, lysine, histidine, glutamine, proline, glutamic acid, or aspartic acid, or a pharmacologically acceptable salt thereof for preventing formation of [[a]] an aggregate of the hepatocyte growth factor, sodium chloride, and a buffering agent, which is prepared from an aqueous solution containing the hepatocyte growth factor at a concentration lower than 5 mg/mL and used for capable of preparing an aqueous solution containing the hepatocyte growth factor at a concentration lower than 5 mg/mL by redissolution.

4. (Currently Amended) The lyophilized preparation according to claim 1, wherein the stabilizing agent is selected from the group consisting of comprises arginine, lysine, histidine, glutamine, proline, glutamic acid, or aspartic acid, sulfated polysaccharides, and or a pharmacologically acceptable salt thereof.

5. (Canceled)

6. (Currently Amended) The lyophilized preparation according to claim 1, wherein the stabilizing agent is selected from the group consisting of arginine, lysine, or histidine, and or a pharmacologically acceptable salt thereof.

7. (Previously Presented) The lyophilized preparation according to claim 1, wherein the buffering agent is a phosphoric acid salt.

8. (Previously Presented) The lyophilized preparation according to claim 1, wherein the aqueous solution before lyophilization has a pH and an osmotic pressure ratio desirable as an injection.

9. (Previously Presented) The lyophilized preparation according to claim 1, wherein the aqueous solution obtained after redissolution has a pH and an osmotic pressure ratio desirable as an injection.

10. (Currently Amended) The lyophilized preparation according to claim [[8]] 1, wherein a pH of the aqueous solution before lyophilization is in the range of 5 to 6.5.

11. (Currently Amended) The lyophilized preparation according to claim [[8]] 2, wherein a pH of the aqueous solution obtained after redissolution is in the range of 5 to 6.5.

12. (Previously Presented) The lyophilized preparation according to claim 1, which further contains a surface active agent.

13. (Original) The lyophilized preparation according to claim 12, wherein the surface active agent is a nonionic surface active agent.

14. (Original) The lyophilized preparation according to claim 13, wherein the nonionic surface active agent is a polyoxyethylene ether surface active agent.

15. (Previously Presented) The lyophilized preparation according to claim 1, which is prepared in a vial or an ampoule.

16. (Currently Amended) The lyophilized preparation according to claim 1, which contains the stabilizing agent in an amount sufficient to prevent HGF aggregate formation during at least one of lyophilization and/or and storage after the lyophilization.

17-21. (Canceled)

22. (New) A method for preparing the lyophilized preparation according to claim 1 comprising lyophilizing an aqueous solution containing the hepatocyte growth factor, the stabilizing agent for preventing formation of an aggregate of the hepatocyte growth factor, the sodium chloride, and the buffering agent, the aqueous solution containing the hepatocyte growth factor at a concentration lower than 5 mg/mL and having a pH in the range of 5.0 to 6.5.

23. (New) The method according to claim 22, wherein the hepatocyte growth factor is dissolved in the aqueous solution.

24. (New) The method according to claim 22, comprising preparing an aqueous solution from the lyophilized preparation, the aqueous solution containing the hepatocyte growth factor at a concentration lower than 5 mg/mL.

25. The method according to claim 22, wherein the stabilizing agent comprises arginine, lysine, histidine, glutamine, proline, glutamic acid, aspartic acid, or sulfated polysaccharides, or a pharmacologically acceptable salt thereof.

26. The method according to claim 22, wherein the stabilizing agent comprises arginine, lysine, histidine, glutamic acid, aspartic acid, or sulfated polysaccharides, or a pharmacologically acceptable salt thereof.

27. The method according to claim 22, wherein the stabilizing agent comprises arginine, lysine, or histidine, or a pharmacologically acceptable salt thereof.

28. (New) The method according to claim 22, comprising preparing an aqueous solution from the lyophilized preparation, the aqueous solution containing the hepatocyte growth factor at a concentration lower than 5 mg/mL.